

RULEMAKING NOTICE FORM

Notice Number 2009-34

Rule Number He-A 304

1. Agency Name & Address: Department of Health and Human Services Bureau of Drug and Alcohol Services 115 Pleasant St. Concord, NH 03301	2. RSA Authority: RSA 318-B:10, VII(b) and VIII(b) 3. Federal Authority: N/A 4. Type of Action: Adoption _____ Amendment _____ Repeal _____ Readoption _____ Readoption w/amendment X
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5. Short Title: **Operational Requirements for Opioid Detoxification and Methadone Maintenance, Treatment and Rehabilitation Programs**

6. (a) Summary of what the rule says and the effect of the rule on those regulated:

He-A 304 describes the requirements necessary to be certified by the New Hampshire bureau of drug and alcohol services as an approved provider of an opioid detoxification and methadone maintenance, treatment and rehabilitation program. The rule is being proposed to prevent expiration on 5/23/09, and is being updated to improve clarity and program integrity.

Proposed changes to the rule include: (1) the requirement of an automated liquid methadone dispensing system; (2) inclusion of parameters for short-term detoxification when client financial obligations are not met; (3) the requirement of programs being open 7 days per week; (4) removal of the requirement for and reporting to a central registry; and (5) the addition of cannabis as a required drug screen substance.

6. (b) Brief description of the groups affected:

This rule affects providers of opioid treatment programs in the state and the clients they serve.

6. (c) Specific section or sections of state statute or federal statute or regulation which the rule is intended to implement:

Rule Section	Statute Implemented
He-A 304 (all sections)	RSA 172:2-a; RSA 318-B:10, VII(b)

7. Contact person for copies and questions including requests to accommodate persons with disabilities:

Name: **Michael Holt**

Title: **Rules Coordinator**

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The proposed rules may be viewed and downloaded at:
<http://www.dhhs.nh.gov/DHHS/ADMINRULEMAKING/default.htm>

8. Deadline for submission of materials in writing or, if practicable for the agency, in the electronic format specified: **Friday, April 24, 2009**

☒ Fax

☒ E-mail

☐ Other format (specify):

9. Public hearing scheduled for:

Date and Time: **Tuesday, April 14, 2009, 10:00 AM**

Place: **DHHS, Brown Bldg. Auditorium, 129 Pleasant St., Concord, NH**

10. Fiscal Impact Statement (Prepared by Legislative Budget Assistant)

FIS # **09:027**, dated **3/10/09**

Fiscal Impact Statement for Department of Health and Human Services rules governing Operational Requirements for Opioid Detoxification and Methadone Maintenance, Treatment and Rehabilitation Programs. [He-A 304]

1. **Comparison of the costs of the proposed rule(s) to the existing rule(s):**

When compared to the existing rules, the proposed rules will increase costs to independently owned businesses by an indeterminable amount.

2. **Cite the Federal mandate. Identify the impact of state funds:**

No federal mandate, no impact on state funds.

3. **Cost and benefits of the proposed rule(s):**

- A. **To State general or State special funds:**

None.

- B. **To State citizens and political subdivisions:**

None.

- C. **To Independently owned businesses:**

The proposed rules require that programs have an automated liquid methadone dispensing system, estimated at a cost of approximately \$3,000 per location. Two currently certified providers operating a total of 5 programs, have such a system in place at each of their locations. One currently certified provider, operating a total of 3 programs, does not currently have such a system which would result in a cost to this provider of \$9,000.

The proposed rules also provide parameters for short-term gradual detoxification of self-pay clients who, due to financial hardship, are unable to continue treatment. Programs currently provide treatment to these clients, and will continue to incur costs based on how much the proposed gradual detoxification timeline is a departure from provider's current practice. Short term detoxification is estimated to be from 1 to 2 weeks, the current fee is estimated to be \$105 per week. Programs generally will not readmit a client until any outstanding balance is paid, so eventually they may be able to recoup these costs. The total cost to providers is indeterminable at this time.

11. Statement Relative to Part I, Article 28-a of the N.H. Constitution:

The proposed rule modifies an existing program and responsibility, but does not mandate any fees, duties or expenditures on the political subdivisions of the state, and therefore does not violate Part I, Article 28-a of the N.H. Constitution.

Readopt with amendment He-A 304, effective 5/23/01 (Document #7496), as amended in He-A 304.03, 304.11, and 304.12, effective 11/20/01 (Document #7599), cited and to read as follows:

CHAPTER He-A 300 CERTIFICATION AND OPERATION OF ALCOHOL AND OTHER DRUG DISORDER TREATMENT PROGRAMS

~~PART He A 304 OPERATIONAL REQUIREMENTS FOR OPIOID DETOXIFICATION AND METHADONE MAINTENANCE, TREATMENT AND REHABILITATION PROGRAMS~~

~~Statutory Authority: RSA 318-B:10, VII(b)~~

~~He A 304.01 Purpose. The purpose of this rule is to describe the necessary structures, criteria, policies, procedure, and practices necessary to be certified as a Division of Alcohol and Drug Abuse Prevention and Recovery approved opioid detoxification, treatment and rehabilitation program. These programs are abstinence oriented, not abstinence mandated. At any point, the client or the staff can request methadone discontinuance.~~

~~He A 304.02 Definitions. The words and phrases used in these rules shall mean the following:~~

~~(a) "Central registry" means information obtained by the department from methadone maintenance and detoxification treatment programs about individuals applying for treatment in order to avoid concurrent enrollment in more than one program.~~

~~(b) "Client" means:~~

~~(1) A person who is receiving a service from a program or community residence; or~~

~~(2) The person's parent or guardian where the rules require the consent or informed decision of the client and he or she is either under the age of 18 and not an emancipated minor or is under guardianship.~~

~~(c) "Division" means the New Hampshire division of alcohol and drug abuse prevention and recovery.~~

~~(d) "Heroin" means "heroin" as defined in RSA 318-B:10, VII(d)(1), namely, "an illegal semi-synthetic drug produced from the morphine contained in sap of the opium poppy, and known to have the potential for devastating addictive properties in vulnerable individuals."~~

~~(e) "Licensed practitioner" means a medical doctor, physician's assistant, advanced registered nurse practitioner, doctor of osteopathy or doctor of naturopathic medicine legally practicing in the State of New Hampshire.~~

~~(f) "Methadone" means "methadone" as defined in RSA 318-B:10, VII(d)(2), namely, "a legal drug, methadone hydrochloride, which is a synthetic opioid that has been demonstrated to be an effective treatment agent for heroin abuse and dependence."~~

~~(g) "Methadone detoxification treatment" means "methadone detoxification treatment" as defined in RSA 318-B:10, VII(d)(3), namely, "the dispensing of methadone or similar substance in decreasing doses to an individual in order to reduce or eliminate adverse physiological or psychological effects incident to the withdrawal from the sustained use of heroin."~~

~~(h) "Methadone maintenance program" means "methadone maintenance program" as defined in RSA 318-B:10, VII(d)(4), namely, "a substance abuse treatment program substituting methadone or any of its derivatives, over time, to relieve withdrawal symptoms of heroin dependence, to reduce craving, and to permit normal functioning and engagement in rehabilitative services."~~

~~—— (i) “Opioids” means a group of morphine-like substances that are:~~

~~(1) One of the following:~~

- ~~a. Directly derived from the opium poppy, such as morphine and codeine;~~
- ~~b. Semi-synthetic substances partially derived from the opium poppy, such as heroin; or~~
- ~~c. Purely synthetic substances, such as hydromorphone and meperidine; and~~

~~(2) Active through specific receptors in the human body;~~

~~—— (j) “Program” means the vehicle by which a provider offers treatment and includes one or more alcohol and other drug abuse treatment services and the associated staff;~~

~~—— (k) “Provider” means any public or private corporation, individual or organization which operates one or more programs for people with alcohol and other drug abuse disorders when such programs are funded in whole or in part by state or federal funds or are operated, monitored or regulated by the division.~~

~~—— He A 304.03 Required Approvals. To be certified under He A 304, an applicant shall:~~

~~—— (a) Be in compliance with He A 301, He A 302, and He A 303;~~

~~—— (b) Have a current accreditation from CARF (Commission on Accreditation of Rehabilitation Facilities) The Rehabilitation Accreditation Commission or its equivalent as an “Opioid Treatment Program” or receive one within 12 months after the opening of the program;~~

~~—— (c) Have CSAT (Center for Substance Abuse Treatment) approval according to 21 CFR 291;~~

~~—— (d) Have a current registration with the DEA according to 21 CFR 1301-1307;~~

~~—— (e) Have a pharmacy in compliance with RSA 318 or be licensed under RSA 318:51-b as a “limited retail drug distributor” as defined in RSA 318:1, VII-a;~~

~~—— (f) Have submitted copies of current documentation of required approvals in (b)-(e) above to the division;~~

~~—— (g) Have set hours of operation and procedures for emergency closure and holiday closures that have been filed with the division; and~~

~~—— (h) Be in compliance with the provisions of He A 304.04-304.13 regarding program operations.~~

~~—— He A 304.04 Screening of Applicants.~~

~~—— (a) Screening shall be the process by which the program staff determines that an applicant is eligible for admission into treatment.~~

~~—— (b) Prior to processing an application for admission, a program shall:~~

- ~~(1) Verify that the applicant meets all the applicable criteria in He A 304; and~~
- ~~(2) Record the sources and methods of verification.~~

~~—(c) Prior to accepting an applicant for treatment, a program shall:~~

- ~~(1) Determine if the applicant needs other specialized services, such as alcoholism treatment or psychiatric services;~~
- ~~(2) Determine if the applicant needs other social supports such as housing, educational, or vocational services; and~~
- ~~(3) Verify that the program is capable of addressing these needs either directly or by referral.~~

~~—(d) In addition to the screening and assessment requirements in He A 302.07, a program that is admitting an applicant shall:~~

- ~~(1) Verify an applicant's identity including:
 - ~~a. Name;~~
 - ~~b. Address;~~
 - ~~c. Date of birth; and~~
 - ~~d. Social security number;~~~~
- ~~(2) Determine by medical examination if the applicant is dependent on an opioid substance;~~
- ~~(3) Take a urine or blood sample, or both, for opioid screening;~~
- ~~(4) Determine and substantiate the duration of the applicant's opioid and other substance dependence;~~
- ~~(5) Verify with the central registry, as required by He A 304.05, that the applicant is not presently a client in another program; and~~
- ~~(6) When an applicant has been discharged from another opioid treatment program, obtain information from that program regarding the reasons for the discharge.~~

~~—(e) Where opioid dependence is verified through other indicators, a negative urine or blood screen shall not preclude admission to the program.~~

~~—(f) A program may re-admit an applicant who voluntarily left methadone maintenance treatment if:~~

- ~~(1) The applicant completed treatment and left the program by mutual agreement of the applicant and program staff;~~
- ~~(2) The applicant is seeking admission within 2 years of discharge;~~
- ~~(3) The applicant does not demonstrate current physiological dependence on an opiate;~~
- ~~(4) The program has documented prior methadone maintenance treatment of 6 months or more; and~~
- ~~(5) The admitting physician finds that, in his/her clinical judgment, opioid treatment is indicated.~~

~~—(g) A methadone treatment and rehabilitation program may accept a pregnant applicant who has a history of opioid dependence without documenting physiological dependence if:~~

~~(1) In the judgment of the medical staff, opioid treatment is indicated; and~~

~~(2) Documented evidence of the pregnancy and a prior history of opioid dependence are entered into the clinical record.~~

~~— (h) An applicant who has resided in a penal or chronic care institution and has a history of opioid dependence may be admitted to a treatment and rehabilitation program without documenting physiological dependence.~~

~~— (i) A program shall only admit an applicant under (h) above if:~~

~~(1) In the judgment of the medical staff, opioid treatment is indicated; and~~

~~(2) The program has obtained documented evidence of the applicant's residence in a penal or chronic care institution and a prior history of opioid dependence.~~

~~— (j) In addition to the requirements of (b) (i) above, during the screening and assessment process for admission into treatment, the following age-related conditions shall be met:~~

~~(1) If an applicant is 21 years of age or older, the program shall verify that applicant's dependence on an opioid substance for a period of at least one year prior to admission;~~

~~(2) If an applicant is under 21 years of age, the program shall verify that applicant's dependence on an opioid substance for a period of 2 years prior to admission;~~

~~(3) A maintenance program shall not admit any person under the age of 18 without documentation of at least 2 prior attempts at detoxification or drug free treatment; and~~

~~(4) An opioid treatment program shall not admit any person under the age of 16 unless pregnant.~~

~~— He A 304.05 Central Registry.~~

~~— (a) In order to prevent simultaneous enrollment of clients in more than one program, the division shall create and maintain a central registry.~~

~~— (b) The information reported to the division shall be treated as confidential in accordance with federal regulations 42 CFR Part 2 and not be released except for treatment purposes or as otherwise required by law.~~

~~— (c) For the purpose of assigning a unique identifier for the client, the reported information shall include:~~

~~(1) The client's first and last initials and the last letter of his or her last name;~~

~~(2) The client's date of birth;~~

~~(3) The last four digits of the client's social security number;~~

~~(4) The anticipated date of admission, transfer, or discharge; and~~

~~(5) The client's gender.~~

~~— (d) A program shall report the information to the division within 2 working days of any admissions, transfers or discharges that are approved by the treatment program.~~

~~(e) The program shall report the information required in (e) above to the division monthly for all active clients that are stabilized on dosages of methadone of 101 milligrams or more or are maintained on dosages of methadone less than 60 milligrams.~~

~~He A 304.06 Admission to a Methadone Maintenance Program.~~

~~(a) Except as required in (b) below, in addition to the requirements of He M 302.07 and 302.08 procedures for admission to an opioid treatment program shall include:~~

- ~~(1) A complete medical history and mental status examination; and~~
- ~~(2) A medical and laboratory examination that shall include, at a minimum:~~

~~a. Screening for the possibility of:~~

- ~~1. Infectious disease;~~
- ~~2. Pulmonary, liver, and cardiac abnormalities;~~
- ~~3. Skin disorders secondary to addiction; and~~
- ~~4. Possible concurrent surgical problems;~~

~~b. Complete blood count and differential;~~

~~c. Screening for all sexually transmitted diseases;~~

~~d. Routine and microscopic urinalysis;~~

~~e. Urine and/or blood screening for drugs as required by He A 304.10;~~

~~f. Multiphasic chemistry profile;~~

~~g. Mantoux test for tuberculosis given and interpreted by the medical staff;~~

~~h. Hepatitis B and C screening;~~

~~i. The following tests, if the examining medical staff determines that any of these tests are indicated:~~

- ~~1. An electrocardiogram;~~
- ~~2. A chest X-ray;~~
- ~~3. A pap smear;~~
- ~~4. A test for pregnancy; and~~
- ~~5. A test for sexually transmitted diseases; and~~

~~j. Tetanus immunization review.~~

~~(b) When a client transferring to a program has received a medical and laboratory examination within 3 months prior to admission. The program shall not conduct a repeat physical and laboratory examination unless requested by the program physician.~~

~~—— (c) The program to which a client transfers shall include copies of the previous examination and laboratory studies in the client's record within 30 days of admission.~~

~~—— (d) An applicant shall sign the federal form FDA-2635 titled "Consent to Methadone Treatment." If the applicant is under 18 years of age, the form shall also be signed by the applicant's parent or legal guardian.~~

~~—— He A 304.07 Medical, Treatment and Rehabilitation Services for a Methadone Maintenance Program.~~

~~—— (a) The program shall have a designated medical director who shall be responsible for all medical services.~~

~~—— (b) The medical director and other licensed practitioners working in the program shall be licensed to practice in the state of New Hampshire and be registered with the Federal Drug Enforcement Administration to administer opioid drugs including methadone.~~

~~—— (c) The medical director shall ensure that every program client:~~

~~(1) An applicant's current physiologic opioid addiction is documented on admission;~~

~~(2) Medical histories, evaluations and, where needed, referrals for additional medical services are completed;~~

~~(3) Appropriate laboratory specimens are collected, analyzed and interpreted within 2 working days of obtaining the samples;~~

~~(4) All medical orders are signed and, where appropriate, counter signed;~~

~~(5) All clients receive an annual medical examination;~~

~~(6) Initial treatment plans and revised/updated treatment plans prepared pursuant to He A 302.08 are reviewed and signed;~~

~~(7) A client's initial and subsequent dose and schedule of methadone are determined and ordered;~~

~~(8) The client's need for methadone maintenance is evaluated at least every 6 months;~~

~~(9) Any controlled substances prescribed for a client are clinically justified and documented in accordance with all applicable regulations, statutes and rules; and~~

~~(10) Other co-occurring psychiatric conditions are treated.~~

~~—— He A 304.08 Treatment Requirements for Methadone Maintenance Program.~~

~~—— (a) Phase I treatment criteria shall be as follows:~~

~~(1) Phase I shall consist of at least a 3 month period in which the client attends the program for observation at least 6 days a week; and~~

~~(2) The client shall receive at least 3 hours of treatment and rehabilitation per week during the initial 3 months following admission.~~

~~—— (b) Phase I treatment shall consist of, at a minimum:~~

- ~~(1) Any combination of individual, group, self help, family counseling or other mental health services totaling 3 hours per week;~~
- ~~(2) Case management services, which may be substituted on an hour for hour basis for any required treatment;~~
- ~~(3) Discussion of the following issues in group treatment, individual sessions, or both:~~
 - ~~a. Working with family or significant others;~~
 - ~~b. Living and coping skills;~~
 - ~~c. Medication and drug education;~~
 - ~~d. Dealing with a positive drug screen;~~
 - ~~e. Education, vocational training, employment, or any combination; and~~
 - ~~f. Education about acquired immunodeficiency syndrome (AIDS) and human immunodeficiency virus (HIV); and~~
- ~~(4) Negotiation between the treatment and rehabilitation team and the client of a methadone discontinuance plan with projected target dates for implementation in phase V, which may:~~
 - ~~a. Be short term or long term in nature based on the client's need and preference; and~~
 - ~~b. Include intermittent periods of methadone maintenance between discontinuance attempts.~~
- ~~———— (c) Transition to phase II treatment shall occur when the following criteria are met:~~
 - ~~(1) The client has successfully completed phase I by having at least 3 months of continuous negative urine or blood screens while in phase I;~~
 - ~~(2) The client has attended for a period of at least 3 months but less than 2 years; and~~
 - ~~(3) The client has not been issued more than 4 take home doses a week.~~
- ~~———— (d) Phase II treatment shall consist of, at a minimum:~~
 - ~~(1) During the first 3 months of phase II, client attendance for at least 2 hours of treatment or rehabilitation per week;~~
 - ~~(2) For the remainder of phase II treatment, client participation in at least one hour of treatment or rehabilitation per week; and~~
 - ~~(3) Case management services, which may be substituted on an hour for hour basis for any required treatment.~~
- ~~———— (e) Transition to phase III treatment shall occur when the following criteria have been met:~~
 - ~~(1) The client has successfully completed phase II by having at least 6 months of continuous negative urine and/or blood screens while in phase II; and~~
 - ~~(2) The client has been admitted more than 2 years but less than 3 years.~~

~~—— (f) Phase III treatment shall consist of, at a minimum:~~

- ~~(1) Issuance by the program of no more than 3 take home doses of methadone to a client at a time and not more than 5 take home doses in a week;~~
- ~~(2) Client participation in at least one hour of treatment or rehabilitation per month; and~~
- ~~(3) Case management services, which may be substituted on an hour for hour basis for any required treatment.~~

~~—— (g) Transition to phase IV treatment shall occur when the following criteria have been met:~~

- ~~(1) The client has successfully completed phase III by having at least 6 months of negative urine and/or blood screens while in phase III; and~~
- ~~(2) The client has been admitted more than 3 years.~~

~~—— (h) Phase IV treatment shall consist of, at a minimum, issuance by the program of not more than a 6-day supply of methadone to a client in a week.~~

~~—— (i) Following consultation with the treatment and rehabilitation team, a client may elect to enter phase V at any time.~~

~~—— (j) Phase V treatment shall consist of, at a minimum:~~

- ~~(1) Discontinuance of methadone in accordance with He A 304.13;~~
- ~~(2) Determination by the program staff, in consultation with the client, of:

 - ~~a. The number of service hours to be provided by staff; and~~
 - ~~b. The number of self-help meetings to be attended by the client;~~~~
- ~~(3) Provision by the program staff of access to the same comprehensive range of medical, treatment, rehabilitative, and pharmacological services as are available to other clients;~~
- ~~(4) An increasing, by the program, of the frequency of treatment and rehabilitation services due to:

 - ~~a. The client's use of controlled substances, except as prescribed; or~~
 - ~~b. Deterioration of the client's social, emotional, vocational or behavioral status; and~~~~
- ~~(5) Requirement by the program of a minimum monthly face-to-face contact between client and staff.~~

~~—— He A 304.09 Take Home Methadone.~~

~~—— (a) Take home methadone may be given to clients under the following circumstances:~~

- ~~(1) Clients require methadone during program holidays and other times when a program is closed; or~~

~~(2) Clients demonstrate a need for a more flexible medication schedule in order to enhance and extend their rehabilitative and community reintegration progress, as judged by a program's clinical staff.~~

~~—— (b) A program's medical and clinical staff shall only give take-home methadone to a client who:~~

~~(1) Is anticipated by the staff to benefit from it;~~

~~(2) Meets the requirements of He A 304.08;~~

~~(3) Adheres to program rules established in accordance with He A 302.04;~~

~~(4) Progresses in rehabilitation as evidenced by:~~

~~a. Absence of alcohol or other drug abuse within the last 3 months;~~

~~b. Participation in treatment in accordance with his or her treatment plan;~~

~~c. Absence of known criminal activity within the previous 6 months; and~~

~~d. Participation in a rehabilitative activity such as:~~

~~1. Employment;~~

~~2. School attendance; or~~

~~3. Volunteer work; and~~

~~(5) Assures the program that take-home medication can be safely transported and stored where the client lives.~~

~~—— (c) Prior to granting take-home privileges, the program physician shall document in the client's record that the criteria in (b) above have been met and that, in his/her judgment, the risk of diversion or misuse is outweighed by the rehabilitative benefits to be derived and the client's demonstrated overall responsibility in the handling of methadone.~~

~~—— (d) The physician shall also provide such documentation each time the client's progress is reviewed as required in He A 302.08(g).~~

~~—— (e) A client for whom take-home methadone is authorized may be provided with one day of extra medication if the client's regular pickup falls on a state holiday.~~

~~—— (f) A program shall permit a client to follow a temporary take-home medication regime provided the following criteria are met:~~

~~(1) The client is unable to conform to the requirements of the applicable phase of treatment because of exceptional circumstances such as:~~

~~a. Illness;~~

~~b. Personal or family crisis;~~

~~c. Travel difficulties, such as bad weather; or~~

~~d. Other hardship that would similarly prevent the client's compliance;~~

~~(2) The program staff find the client to be responsible in using methadone as required in He A 304.09(d);~~

~~(3) The program physician has determined that a reduced schedule is appropriate;~~

~~(4) The client is not given more than a 2-week supply of methadone at one time;~~

~~(5) The reasons for permitting a temporarily reduced schedule have been recorded by program staff in the client's record; and~~

~~(6) The effectiveness of the temporary take-home regime is evaluated by program staff.~~

~~—— (g) All dispensed medication shall be labeled in accordance with He A 302.10(b), (q), (r), (s), and (ag), and within the provisions outlined in RSA 318-B:13.~~

~~—— He A 304.10 Urine and/or Blood Screens. In addition to the requirements of He A 302.06(b)(8), a program shall perform, or have performed, tests of clients as follows:~~

~~—— (a) All new clients shall have a minimum of a urine or blood screen upon admission and randomly every week thereafter for the first 3 months of treatment;~~

~~—— (b) A minimum of monthly random urine or blood screens shall be collected from each client while in treatment;~~

~~—— (c) All required urine or blood screens shall include, at a minimum, the following substances, unless otherwise documented in the client record by staff:~~

~~(1) Opiates;~~

~~(2) Methadone;~~

~~(3) Amphetamines;~~

~~(4) Cocaine;~~

~~(5) Benzodiazepines; and~~

~~(6) Barbiturates; and~~

~~—— (d) For females of childbearing age, a program shall:~~

~~(1) Evaluate, by counselor interview, the risk of pregnancy;~~

~~(2) If risk is found to be positive, order a pregnancy confirmation test; and~~

~~(3) If pregnancy is confirmed:~~

~~a. Refer the client for health care for her pregnancy; and~~

~~b. Coordinate her treatment with her health care provider;~~

~~—— (e) If a pregnant client refuses to obtain primary care for her pregnancy, program staff shall ask the client to sign a statement indicating she has refused such care; and~~

~~—— (f) A program shall test monthly for pregnancy any female client of childbearing age who is using buprenorphine.~~

~~—— He A 304.11 Short Term Detoxification Treatment. For short term inpatient or outpatient detoxification from opioids, methadone or buprenorphine shall be administered as follows:~~

~~—— (a) Methadone or buprenorphine shall be administered daily;~~

~~—— (b) Take home medications shall not be allowed during short term detoxification except as allowed in He A 304.09;~~

~~—— (c) A history of one year physiologic dependence shall not be required for admission to short term detoxification;~~

~~—— (d) Clients who have been determined by the program physician to be currently physiologically opioid dependent may be placed in short term detoxification treatment, regardless of age;~~

~~—— (e) No urine or blood test or analysis shall be required except for the initial drug screen;~~

~~—— (f) Treatment planning for short term clients shall be as follows:~~

~~(1) The initial treatment plan and periodic treatment plan required for maintenance clients shall not be required for short term detoxification clients; and~~

~~(2) A summary of information gathered from the screening process required in He A 304.04 shall be entered into the client record;~~

~~—— (g) The requirement for the “Consent to Methadone Treatment” Form FDA-2635 shall not apply to short term detoxification treatment;~~

~~—— (h) Before a short term detoxification attempt is repeated, the program physician shall document in the client’s record that the client continues to be or, is again, physiologically dependent on opioids; and~~

~~—— (i) Short term detoxification treatment shall only be used for a pregnant client if maintenance treatment has been determined by the treating physician to be ineffective.~~

~~—— He A 304.12 Long Term Detoxification Treatment.~~

~~—— (a) Methadone and buprenorphine shall be administered in a way designed for a client to reach a drug-free state and to make progress in rehabilitation in 180 days or less.~~

~~—— (b) All requirements of He A 304.08 for maintenance treatment shall apply to long term detoxification treatment with the following exceptions:~~

~~(1) Methadone and buprenorphine shall be administered daily;~~

~~(2) Take home medications shall not be allowed during long term detoxification except as allowed in He A 304.09;~~

~~(3) A history of one year physiologic dependence shall not be required for admission to long-term detoxification;~~

- ~~(4) The program physician shall document in the client's record that short term detoxification is not sufficiently long enough to provide the client with the additional services and supports the physician deems necessary for the client's rehabilitation;~~
- ~~(5) Clients who have been determined by the program physician to be currently physiologically dependent on opioids may be placed, at the physician's discretion, in long term detoxification treatment regardless of age;~~
- ~~(6) Drug screens shall be performed as follows:~~
- ~~a. An initial drug screen shall be performed for each client; and~~
 - ~~b. At least one additional random screen shall be performed monthly on each client during long term detoxification;~~
- ~~(7) Before the long term detoxification attempt is repeated, the program physician shall document in the client's record that the client continues to be or is again physiologically dependent on opioids; and~~
- ~~(8) The requirements in (1) (8) above shall apply to both inpatient and outpatient long term detoxification treatment.~~
- ~~He A 304.13 Discontinuance of Methadone. Each program shall develop policies for the discontinuance of methadone that, at a minimum, specify that:~~
- ~~(a) The discontinuance shall be provided to all clients who request it;~~
 - ~~(b) The determination to voluntarily discontinue methadone shall be left to the judgment of the client, in consultation with the staff of the program;~~
 - ~~(c) If the staff of the program does not agree with the client's decision to discontinue methadone, the staff shall document the difference in the client's record;~~
 - ~~(d) Reduction of a client's methadone dosage shall:~~
 - ~~(1) Be ordered and overseen by medical staff of the program;~~
 - ~~(2) Occur gradually in a manner that facilitates the client's withdrawal, as determined by the medical staff; and~~
 - ~~(3) Be in accordance with the client's treatment goals;~~
 - ~~(e) In situations where medical staff have determined that onsite discontinuance is undesirable, such as due to the client's violent behavior:~~
 - ~~(1) Alternative arrangements shall be offered by the program staff; and~~
 - ~~(2) If the client refuses all of the arrangements, the refusal shall be documented by program staff in the clinical record;~~
 - ~~(f) Programs shall have procedures that permit the timely and orderly re-admission of the client in the event of a relapse;~~

~~— (g) Continued services and supports necessary to support the client through the discontinuance process shall be provided by the program in consultation with the clinical staff;~~

~~— (h) Continued services and supports necessary to support the client after the discontinuance process shall be provided by the program in consultation with the clinical staff; and~~

~~— (i) Programs shall have discharge policies as required by He A 302.06(b)(15).~~

~~— He A 304.14 Security of Drugs. In addition to being compliant with DEA regulations 21 CFR 1301-1307 and He A 302.10, a program shall:~~

~~— (a) Limit access to secure areas where methadone is stored and dispensed to staff licensed, registered, or certified to order, prepare, dispense, or administer methadone;~~

~~— (b) Arrange that the area where methadone is stored and dispensed is securely and physically separate from the client and visitor areas;~~

~~— (c) Select and install alarm systems in such a way so that codes and locks can be changed following the termination of an employee authorized under (a) above;~~

~~— (d) Notify the division in writing of any theft, attempted theft, loss or spillage of any methadone and send copies of DEA reporting forms to the division; and~~

~~— (e) Handle containers as follows:~~

~~(1) Immediately after administration, containers shall be purged by rinsing, inversion, or by an alternative method that prevents the accumulation of residual methadone;~~

~~(2) Used containers shall be destroyed, including those containers used in the program as well as all take home bottles dispensed to clients in maintenance type programs; and~~

~~(3) Maintenance clients shall return take home bottles before receiving further take home medication.~~

~~— He A 304.15 Hours of Operation.~~

~~— (a) A program shall be open at least 6 days a week.~~

~~— (b) Dispensing hours shall be flexible enough to permit a client who is working or attending school to receive his or her methadone without jeopardizing such work or school.~~

~~— (c) A program shall maintain hours of operation that:~~

~~(1) Include day, evening or both and weekend hours to accommodate client need; and~~

~~(2) Permit clients to receive medication individually and within 15 minutes of their scheduled appointments.~~

~~— (d) A program shall not close for holidays except for state holidays.~~

~~— He A 304.16 Community Concerns.~~

~~— (a) A program shall assure that its clients do not cause unnecessary disruption to the community by loitering near the program or acting in a manner that would constitute disorderly conduct or harassment.~~

~~———— (b) Clients who consistently cause disruption to the community or to the program shall be evaluated for possible discharge from the program pursuant to the program's policies.~~

~~———— (c) Each program shall provide to the division, upon request, a specific plan describing its efforts to avoid disruption of the community and actions it will take to respond to community concerns.~~

~~———— (d) If the division determines that the program's plan is not sufficient to avoid disruption to the community, the program shall:~~

~~(1) Assign a staff member to act as community liaison;~~

~~(2) Establish a hot line between the community and the program administration;~~

~~(3) Assign staff to patrol the immediate vicinity; or~~

~~(4) Form a committee including representatives from the community to meet on a regular basis to assist in the resolution of the disruption.~~

~~———— He A 304.17 Waivers.~~

~~———— (a) An agency or individual may request a waiver of a specific provision or procedure of He A 304.~~

~~———— (b) A program seeking waivers of specific rules in He A 304 shall submit a written request for waiver to the director that includes:~~

~~(1) Specific reference to the rule for which a waiver is being sought;~~

~~(2) Full explanation of why a waiver is necessary; and~~

~~(3) Full explanation of alternatives proposed by the applicant.~~

~~———— (c) No provision or procedure prescribed by statute shall be waived.~~

~~———— (d) The director shall approve a request for waiver if:~~

~~(1) Strict compliance with the provision or procedure sought to be waived will not negatively impact client care;~~

~~(2) The director concludes that authorizing deviation from strict compliance with the rule from which waiver is sought does not contradict the intent of the rule; and~~

~~(3) One of the following applies:~~

~~a. The alternative provisions or procedures proposed by the applicant are at least equivalent to the specific provisions or procedures contained in the rule; or~~

~~b. The alternative provisions or procedures proposed by the applicant are not equivalent to the provisions or procedures contained in the rule but are sufficient to ensure that the objective or intent of the relevant rule will be accomplished.~~

~~———— (e) The applicant's subsequent compliance with the alternatives approved in the waiver shall be considered equivalent to complying with the rule from which the waiver was sought.~~

~~——(f) Waivers shall not be transferable.~~

~~——(g) Waivers shall be granted in writing for a specific duration which shall not exceed either one year or any period of certification, whichever comes first.~~

~~——(h) The applicant may request a renewal of the waiver from the director. Such request shall be made at least 90 days prior to the expiration of the current waiver.~~

PART He-A 304 OPERATIONAL REQUIREMENTS FOR OPIOID DETOXIFICATION AND METHADONE MAINTENANCE, TREATMENT AND REHABILITATION PROGRAMS

Statutory Authority: RSA 318-B:10, VII(b) and VIII(b)

He-A 304.01 Purpose. The purpose of these rules is to describe the requirements necessary to be certified by the New Hampshire bureau of drug and alcohol services as an approved provider of an opioid detoxification and methadone maintenance, treatment, and rehabilitation program.

He-A 304.02 Definitions. The words and phrases used in these rules shall mean the following:

(a) “Buprenorphine” means a semi-synthetic opiate with partial agonist actions used in the treatment of opiate addiction.

(b) “Bureau” means the New Hampshire bureau of drug and alcohol services.

(c) “Client” means a person who is enrolled in a program and is receiving services from a provider certified by these rules.

(d) “Heroin” means “heroin” as defined in RSA 318-B:10, VII(d)(1), namely, “an illegal semi-synthetic drug produced from the morphine contained in sap of the opium poppy, and known to have the potential for devastating addictive properties in vulnerable individuals.”

(e) “Licensed practitioner” means a medical doctor, physician’s assistant, advanced registered nurse practitioner, doctor of osteopathy or doctor of naturopathic medicine legally practicing in the State of New Hampshire.

(f) “Methadone” means “methadone” as defined in RSA 318-B:10, VII(d)(2), namely, “a legal drug, methadone hydrochloride, which is a synthetic opiod that has been demonstrated to be an effective treatment agent for heroin abuse and dependence.”

(g) “Methadone detoxification treatment” means “methadone detoxification treatment” as defined in RSA 318-B:10, VII(d)(3), namely, “the dispensing of methadone or similar substance in decreasing doses to an individual in order to reduce or eliminate adverse physiological or psychological effects incident to the withdrawal from the sustained use of heroin.”

(h) “Methadone maintenance program” means “methadone maintenance program” as defined in RSA 318-B:10, VII(d)(4), namely, “a substance abuse treatment program substituting methadone or any of its derivatives, over time, to relieve withdrawal symptoms of heroin dependence, to reduce craving, and to permit normal functioning and engagement in rehabilitative services.”

(i) “Opioids” means a group of morphine-like substances that are:

(1) One of the following:

- a. Directly derived from the opium poppy, such as morphine and codeine;
- b. Semi-synthetic substances partially derived from the opium poppy, such as heroin; or
- c. Purely synthetic substances, such as hydromorphone and meperidine; and

(2) Active through specific receptors in the human body.

(j) “Program” means an opioid treatment program which provides opioid detoxification and methadone maintenance, treatment, and rehabilitation services.

(k) “Provider” means any public or private corporation, individual or organization which operates one or more programs for people with alcohol and other drug abuse disorders when such programs are funded in whole or in part by state or federal funds or are operated, monitored or regulated by the bureau.

He-A 304.03 Required Approvals. To be certified under He-A 304, an applicant for certification shall:

- (a) Be in compliance with He-A 301, He-A 302, He-A 303, and 304;
- (b) Have either:
 - (1) A current accreditation as an opioid treatment program (OTP) from the Commission on Accreditation of Rehabilitation Facilities (CARF) or another Substance Abuse and Mental Health Services Administration (SAMHSA)-approved OTP accrediting body; or
 - (2) A provisional certification as an OTP from SAMHSA;
- (c) Have a current registration with the U.S. Drug Enforcement Administration in accordance with 21 CFR 1301-1307;
- (d) Have a pharmacy in compliance with RSA 318:51-b and licensed in accordance with Ph 600 as a limited retail drug distributor as defined in RSA 318:1, VII-a;
- (e) Be in compliance with local planning and zoning ordinances;
- (f) Have submitted copies of current documentation of required approvals in (b)-(e) above to the bureau;
- (g) Have set hours of operation and procedures for emergency closure and holiday closures that have been filed with the bureau; and
- (h) Have an automated liquid methadone dispensing system.

He-A 304.04 Client Eligibility. A program shall determine eligibility for admission in accordance with 42 CFR Part 8, Section 8.12 (e).

He-A 304.05 Opportunity To Participate in Detoxification Treatment Required.

- (a) The medical director shall ensure, and shall document, that each client is offered the opportunity to participate in a methadone or buprenorphine detoxification treatment program instead of a maintenance treatment program at the time of admission and at least every 6 months thereafter.
- (b) When clinically appropriate, the medical director shall encourage clients to choose a methadone or buprenorphine detoxification treatment program over a maintenance treatment program.
- (c) The medical director shall document in the client’s record the clinical appropriateness of the form of treatment chosen.

He-A 304.06 Required Medical, Treatment and Rehabilitation Services.

- (a) The program shall have a designated medical director who shall be responsible for all medical services.

(b) The medical director shall ensure that, for every program client:

- (1) Treatment plans are prepared and updated pursuant to He-A 302.08 and these rules;
- (2) The client's need for methadone maintenance is evaluated at least every 6 months;
- (3) Any controlled substances prescribed for a client are clinically justified and documented in accordance with all applicable regulations, statutes and rules; and
- (4) A determination is made regarding the client's need for any other specialized services, such as alcoholism or psychiatric services, and any such conditions are identified and treated or a referral is made to an appropriate service provider.

He-A 304.07 Treatment Requirements for Long-Term Detoxification.

(a) For each client participating in long-term detoxification, the program shall administer methadone or buprenorphine in a way designed for a client to reach a drug-free state and to make progress in rehabilitation within a period of between 90 and 180 days, as follows:

- (1) The program shall maintain the client with a dose adequate to alleviate all withdrawal symptoms;
- (2) The program shall establish client dosing based on individual need, as detailed in the client's treatment plan;
- (3) The program shall provide flexible dosage tapering at the client's request.

(b) All requirements of He-A 304.09 for maintenance treatment shall apply to long-term detoxification treatment with the following exceptions:

- (1) Take-home medications shall not be allowed during long-term detoxification except as allowed for state holidays and special circumstances as outlined in He-A 304.10(c) and (d);
- (2) A history of one-year physiologic dependence shall not be required for admission to long-term detoxification;
- (3) The medical director shall document in the client's record that short-term detoxification is not sufficiently long enough to provide the client with the additional services and supports the physician deems necessary for the client's rehabilitation;
- (4) Clients who have been determined by the program physician to be currently physiologically dependent on opioids may be placed, at the physician's discretion, in long-term detoxification treatment regardless of age;
- (5) Drug screens shall be performed as follows:
 - a. An initial drug screen shall be performed for each client; and
 - b. At least one additional random screen shall be performed monthly on each client during long-term detoxification;

(6) Before the long-term detoxification attempt is repeated, the program physician shall document in the client's record that the client continues to be or is again physiologically dependent on opioids; and

(7) The requirements in (1)-(6) above shall apply to both inpatient and outpatient long-term detoxification treatment.

He-A 304.08 Treatment Requirements for Short-Term Detoxification.

(a) For each client participating in short-term detoxification, the program shall administer methadone or buprenorphine in a way designed for a client to reach a drug-free state within a period no longer than 21 days, excluding the time needed for the program to maintain the client with a dose adequate to alleviate all withdrawal symptoms, as follows:

(1) The program shall maintain the client with a dose adequate to alleviate all withdrawal symptoms;

(2) The program shall establish client dosing based on individual need, as detailed in the client's treatment plan;

(3) The program shall provide flexible dosage tapering at the client's request;

(4) The program shall develop a detoxification schedule of no more 21 days long with daily dosage reductions less than 5 percent of the original dose; and

(5) The program shall conduct daily observation of the client, monitoring for withdrawal symptoms.

(b) For each client participating in short-term detoxification, the following program requirements shall apply:

(1) Methadone or buprenorphine shall be administered daily;

(2) Take-home medications shall not be allowed during short-term detoxification;

(3) A history of one-year physiologic dependence shall not be required for admission to short-term detoxification;

(4) No urine or blood test or analysis shall be required except for the initial drug screen;

(5) Short-term detoxification shall not be repeated unless the medical director document in the client's record that the client continues to be or, is again, physiologically dependent on opioids;

(6) Subsequent short-term detoxifications allowed in (7) above shall be limited to one additional short-term detoxification in one 12-month period, in accordance with 42 CFR Part 8; and

(7) Short-term detoxification treatment shall only be used for a pregnant client if maintenance treatment has been determined by the treating physician to be ineffective.

He-A 304.09 Treatment Requirements for Methadone Maintenance.

(a) Based on the client's treatment plan, methadone maintenance treatment shall include:

- (1) Daily methadone doses, either administered on site at a program facility or as unsupervised take-home doses;
 - (2) Client counseling and rehabilitation;
 - (3) Urine and/or blood screening; and
 - (4) Over time, the gradual decrease in the number of required hours of counseling, and an increase in the allowable number of take-home methadone doses per week.
- (b) During the first 90 days of treatment, clients shall:
- (1) Attend the program 7 days per week for observation and on-site administration of methadone;
 - (2) Participate in 3 hours of counseling per week; and
 - (3) Not be provided with any take-home methadone doses, except as detailed in He-A 304.10 below.
- (c) Every 90 days, upon a client's compliance with required treatment and counseling and the negative results for all urine and blood screens conducted:
- (1) The required number of hours of counseling shall be reduced by one half-hour; and
 - (2) The allowed number of take-home methadone doses shall be increased by one dose.

Table 304.1 Treatment, Counseling, and Take-Home Schedule

Days in Treatment	Required Hours of Counseling	Allowed Doses of Take-Home Methadone
1-90	3	0
91-180	2.5	1
181-270	2	2
271- 360	1.5	3
361-450	1	4
451-540	0.5	5
541+	0	6

- (d) No program shall issue more than a 6-day supply of take-home methadone to a client in one week.
- (e) Regardless of the time already spent in treatment, a client who has a positive urine and/or blood screen shall be required to comply with the requirements in (b) above.
- (f) Required counseling shall include, at a minimum:
- (1) Any combination of individual, group, self-help, or family counseling or other mental health services;
 - (2) Case management services, which may be substituted on an hour-for-hour basis for any required counseling;
 - (3) Discussion of the following issues in group counseling, individual sessions, or both:
 - a. Working with family or significant others;
 - b. Living and coping skills;

- c. Medication and drug education;
- d. Dealing with a positive drug screen;
- e. Education, vocational training, employment, or any combination thereof; and
- f. Education about acquired immunodeficiency syndrome (AIDS) and human immunodeficiency virus (HIV); and

(4) Discussion between the treatment and rehabilitation team and the client regarding the commencement of a methadone discontinuance plan, with projected target dates for implementation, which may:

- a. Be short-term or long-term in nature based on the client's need and preference; and
- b. Include intermittent periods of methadone maintenance between discontinuance attempts.

(g) Documentation of methadone treatment shall be maintained in the client's record.

He-A 304.10 Unsupervised Take-Home Methadone.

(a) A program's medical and clinical staff shall only give take-home methadone to a client who meets the take-home criteria in accordance with 42 CFR Part 8.12(h)(4)(i)(2).

(b) In addition to the criteria in (a) above, a client shall complete individual or group counseling specific to the safe transport and storage of take-home medication to prevent diversion, theft, or use by another person, each time the client is eligible for consideration of an additional unsupervised take-home dose.

(b) Prior to granting take-home privileges, and each time the client's progress is reviewed, the medical director shall document in the client's record that the criteria in (a) above have been met and that, in his or her judgment, the potential risk of diversion or misuse is outweighed by the rehabilitative benefits to be derived from decreasing the frequency of clinic attendance and the client's demonstrated overall responsibility in the handling of methadone.

(c) A client for whom take-home methadone is authorized may be provided with one day of extra medication if the client's regular pickup falls on a state holiday.

(d) For clients who demonstrate a need for a more flexible take-home methadone schedule in order to enhance and extend their rehabilitative and community reintegration progress, a program may request of the state methadone authority, the department, approval to permit a client to follow a temporary take-home medication regimen.

(e) The department shall approve such requests in (d) above if it determines that:

(1) The client is unable to comply with the required treatment, counseling, and/or take-home schedule because of exceptional circumstances such as:

- a. Illness;
- b. Personal or family crisis;
- c. Travel difficulties, such as bad weather; or

d. Other hardship that would similarly prevent the client's compliance;

(2) The medical director has found the client to be responsible in using methadone as required in (b) above;

(3) The medical director has determined that a temporarily reduced clinic attendance schedule is appropriate;

(4) The client is not given more than a 2-week supply of methadone at one time;

(5) The reasons for permitting a temporarily reduced clinic attendance schedule have been recorded by program staff in the client's record; and

(6) Program staff have evaluated the effectiveness of the temporary take-home regimen; and

(7) The medical director has submitted such exception requests on-line, using the SAMHSA OTP Exception Request Web site at <http://www.dpt.samhsa.gov/regulations/exrequests.aspx>.

(f) All dispensed medication shall be labeled in accordance with He-A 302.10(b), (q), (r), (s), and (ah), and within the provisions outlined in RSA 318-B:13.

He-A 304.11 Discontinuance of Methadone.

(a) The discontinuance of methadone shall be provided to all clients who request it.

(b) The determination to voluntarily discontinue methadone shall be left to the judgment of the client, in consultation with the staff of the program.

(c) If the staff of the program do not agree with the client's decision to discontinue methadone, the staff shall document the difference in the client's record.

(d) Reduction of a client's methadone dosage shall:

(1) Be ordered and overseen by medical staff of the program;

(2) Occur gradually in a manner that facilitates the client's withdrawal, as determined by the medical staff; and

(3) Be in accordance with the client's treatment goals.

(e) In situations where medical staff have determined that onsite discontinuance is undesirable, such as due to the client's violent behavior:

(1) Alternative arrangements shall be offered by the program staff; and

(2) If the client refuses all of the arrangements, the refusal shall be documented by program staff in the clinical record.

(f) Programs shall have procedures that permit the timely and orderly re-admission of the client in the event of a relapse.

(g) Continued services and supports necessary to support the client through and after the discontinuance process shall be provided by the program in consultation with the clinical staff.

(h) Programs shall have discharge policies as required by He-A 302.06(b)(15).

He-A 304.12 Urine and Blood Screens.

(a) In addition to the requirements of He-A 302.06(b)(8), a program shall perform, or have performed, tests of clients as described in (b)-(f) below.

(b) All new clients shall have a minimum of a urine or blood screen upon admission and randomly every week thereafter for the first 3 months of treatment.

(c) A minimum of monthly random urine or blood screens shall be collected from each client while in treatment.

(d) All required urine or blood screens shall include, at a minimum, the following substances, unless otherwise documented in the client record by staff:

- (1) Opiates;
- (2) Methadone;
- (3) Amphetamines;
- (4) Cocaine;
- (5) Benzodiazepines;
- (6) Barbiturates; and
- (7) Cannabis.

(e) A program shall test monthly for pregnancy any female client of childbearing age who is using buprenorphine.

(f) For all other females of childbearing age, a program shall:

- (1) Evaluate, by counselor interview, the risk of pregnancy;
- (2) If risk is found to be positive, order a pregnancy confirmation test; and
- (3) If pregnancy is confirmed:
 - a. Refer the client for health care for her pregnancy; and
 - b. Coordinate her treatment with her health care provider.

(g) If a pregnant client refuses to obtain primary care for her pregnancy, program staff shall ask the client to sign a statement indicating she has refused such care.

He-A 304.13 Administrative Discharge.

(a) A program may administratively discharge a client from a treatment program only if:

- (1) The client's behavior on program premises is abusive, violent, or illegal;

(2) The client fails to pay fees after being informed in writing and counseled regarding financial responsibility and possible sanctions including discharge;

(3) The client misses 3 consecutive medication days, and the medical director, after a reevaluation of the client, has determined that administrative discharge is warranted; or

(4) Clinical staff documents therapeutic reasons for discharge, which may include the client's continued use of illicit drugs or an unwillingness to follow appropriate clinical interventions.

(b) If a client is administratively discharged due to financial reasons in (a)(2) above, the program shall provide short-term detoxification in accordance with He-A 304.08, regardless of the client's ability to pay.

He-A 304.14 Client Transfer between Programs.

(a) When a client transferring to a program has received a medical and laboratory examination within 3 months prior to admission, the program shall not conduct a repeat physical and laboratory examination unless requested by the medical director.

(b) The program to which a client transfers shall include copies of the previous examination and laboratory studies in the client's record within 30 days of admission.

(c) Upon receipt of an appropriately executed release of information, a program shall provide to the receiving program the client's clinical record, including attendance, dosage, previous three drug screens, and all pertinent medical information, even if the client still has an outstanding financial balance.

(d) Clients who are in good standing at their previous methadone or buprenorphine opiate treatment program may be accepted as a transfer client and continue to receive unsupervised take home doses at the same level, not to exceed 6 take home doses per week, as long as the receiving program has verified the client's compliance in their previous program.

He-A 304.15 Security of Drugs. In addition to being compliant with DEA regulations 21 CFR 1301-1307 and He-A 302.10, a program shall:

(a) Limit access to secure areas where methadone is stored and dispensed to staff licensed, registered, or certified to order, prepare, dispense, or administer methadone;

(b) Arrange that the area where methadone is stored and dispensed is securely and physically separate from the client and visitor areas;

(c) Select and install alarm systems in such a way so that codes and locks can be changed following the termination of an employee authorized under (a) above;

(d) Notify the bureau in writing of any theft, attempted theft, loss, or spillage of any methadone and send copies of DEA reporting forms to the bureau; and

(e) Handle containers as follows:

(1) Immediately after administration, containers shall be purged by rinsing, inversion, or by an alternative method that prevents the accumulation of residual methadone;

(2) Used containers shall be destroyed, including those containers used in the program as well as all take-home bottles dispensed to clients in maintenance-type programs; and

(3) Maintenance clients shall return take-home bottles before receiving further take-home medication.

He-A 304.16 Hours of Operation.

- (a) A program shall be open 7 days a week.
- (b) Dispensing hours shall be flexible enough to permit a client who is working or attending school to receive his or her methadone without jeopardizing such work or school.
- (c) A program shall maintain hours of operation that:
 - (1) Include day, evening, or both, and weekend hours to accommodate client need; and
 - (2) Permit clients to receive medication individually and within 15 minutes of their scheduled appointments.
- (d) A program shall not close for holidays except for state holidays.

He-A 304.17 Community Concerns.

- (a) A program shall assure that its clients do not cause unnecessary disruption to the community by loitering near the program or acting in a manner that would constitute disorderly conduct or harassment.
- (b) Clients who consistently cause disruption to the community or to the program shall be evaluated for possible discharge from the program pursuant to the program's policies.
- (c) Each program shall provide to the bureau a specific plan describing its efforts to avoid disruption of the community and actions it will take to respond to community concerns.
- (d) If the bureau determines that the program's plan is not sufficient to avoid disruption to the community, the program shall provide the bureau with a written corrective action plan, within 10 days, including time lines for implementation.

He-A 304.18 Client Grievances. The program shall have a written policy for handling client grievances, including specific time frames for written responses to the client's written request for consideration or reconsideration of a program decision.

He-A 304.19 Waivers.

- (a) A program may request a waiver of a specific provision or procedure of He-A 304, in writing, from the department.
- (b) A request for a waiver shall include:
 - (1) A specific reference to the section of the rule for which a waiver is being sought;
 - (2) A full description of why a waiver is necessary; and
 - (3) A full explanation of alternative provisions or procedures proposed by the applicant.
- (c) No provision or procedure prescribed by statute shall be waived.

(d) A request for a waiver shall be granted after the commissioner or his or her designee determines that the alternative proposed by the applicant:

- (1) Meets the objective or intent of the rule;
- (2) Does not negatively impact the health or safety of clients; and
- (2) Does not affect the quality of provider services.

(e) Upon receipt of approval of a waiver request, the applicant's subsequent compliance with the alternative provisions or procedures approved in the waiver shall be considered compliance with the rule for which the waiver was sought.

(f) Waivers shall not be transferable.

(g) Waivers shall be granted in writing for a specific duration which shall not exceed 3 years except as in (h) below, or until the end of the current certification period.

(h) The applicant may request a renewal of the waiver from the department. Such request shall be made at least 90 days prior to the expiration of the current waiver.

Appendix

<u>Rule Section</u>	<u>RSA Implemented</u>
He-A 304 (all sections)	RSA 172:2-a; RSA 318-B:10, VII(b)